

**REMARKS/ARGUMENTS**

Claims 1-23 have been revised to be dependent from claim 31. Claim 1 has been revised to conform its language to that of claim 31, while claims 3, 10, 12, 18, and 23 have been revised to remove extraneous language.

Claims 24-30 and 122-142 have been canceled without prejudice for re-presentation in a continuing application, such as a divisional application.

Claims 31 and 69 have been revised to better tailor the claim to currently contemplated commercial embodiments of the invention. Support for the revisions is found at least on page 7, third full paragraph, of the instant specification. Any change in claim scope is not made for any reason related to patentability.

Claims 37, 42, 46, 49, 52-54, 61, 66, 70, 73, 74, 76, 78-80, and 82 have been revised to remove extraneous language and to assist with the understanding of the nature of the claimed invention.

Claims 82-89 have been revised to be dependent from claim 71. Claim 83 has been revised to conform its language to that of claim 71, while claims 84, 85, 87, and 89 have been revised to remove extraneous language and to assist with the understanding of the nature of the claimed invention.

Claims 90, 91, 95, 100, 105, and 106 have been revised to remove extraneous language and to assist with the understanding of the nature of the claimed invention.

Claims 112-121, 143-145, and 146-150 have been revised to be dependent from claim 31.

No new matter has been introduced, and entry of the above revised claims is respectfully requested.

Applicants point out that the method claims now dependent from composition claims are subject to rejoinder should the composition claims be found allowable. Acknowledgement of the applicability of rejoinder is respectfully requested.

Telephonic Interview of May 31, 2006

Applicants thank Examiner Macias for the courtesy of a brief telephonic interview on May 31, 2006 to confirm that the first Restriction Requirement mailed April 12, 2006 was vacated in favor of the Restriction Requirement mailed April 26, 2006. Applicants also confirm their understanding from Examiner Macias that the two Restriction Requirements are identical.

Restriction Requirement

Reconsideration and modification or withdrawal of the Restriction Requirement is respectfully requested in light of the following remarks. As an initial matter, Applicants point out that the invention is directed to a composition, or combination, of materials wherein there a specific relationship between the components of the composition. See for example, claims 31 and 69.

The Restriction Requirement sets forth the following Groups:

- Group XIV, claims 31-82 and 90-111;
- Group XV, claims 31-82 and 90-111;
- Group XVI, claims 31-82 and 90-111;
- Group XVII, claims 31-82 and 90-111;
- Group XVIII, claims 31-82 and 90-111;
- Group XIX, claims 31-82 and 90-111;
- Group XX, claims 31-82 and 90-111;
- Group XXI, claims 31-82 and 90-111;
- Group XXII, claims 31-82 and 90-111;
- Group XXIII, claims 31-82 and 90-111;
- Group XXIV, claims 31-82 and 90-111; and
- Group XXV, claims 31-82 and 90-111.

The Requirement alleges that each of the above 12 Groups (XIV to XXV) is an invention relating to a composition comprising one or more ligands that bind one of 12 Toll-like

receptors (or “TLRs”) numbered from TLR-1 to TLR-12. But Applicants respectfully point out that claims 31-45, 47, 48, 50, 51, 63-65, 69-82, and 90-99, as non-limiting examples, are generic (or genus) claims. As an example, claims 31 and 69 are directed to a composition comprising “a ligand for the pattern recognition molecule family of receptors” and “at least one ligand for a pattern recognition receptor molecule”, respectively. Like claim 69, claim 90 also recites “at least one ligand for a pattern recognition receptor molecule”.

A generic, or genus, claim is defined at MPEP 806.04(d). At least claims 31-45, 47, 48, 50, 51, 63-65, 69-82, and 90-99 are generic, or genus, claims within that definition. For example, these claims do not limit the ligand to those that only bind to one of the TLR-1 to TLR-12 receptor molecules. No reason has been provided as to why these claims are not generic, or genus, claims within the definition set forth at MPEP 806.04(d).

Recognition of the presence of genus claims is important because Applicant regards the genus as the invention. Any attempt to restrict the genus to be merely species thereof would deny Applicant the ability to seek claims directed to what she regards as the invention. See *In re Weber* (580 F.2d 455, 198 USPQ 328 (CCPA 1978)) and *In re Haas* (580 F.2d 461, 198 USPQ 334 (CCPA 1978)), and the discussion at MPEP 803.02 in a related context. These cases clearly set forth that a restriction requirement cannot be used to divide a single claim, such as a genus claim. Therefore, and by way of example, claims 31-45, 47, 48, 50, 51, 63-65, 69-82, and 90-99 cannot be divided by restriction, such as by their inclusion in Groups XIV to XXV with an artificially imposed limitation to only ligands which bind one of 12 TLR molecules.

The fact that restriction contrary to *Weber* and *Haas* has occurred is seen in the case of claims 63 and 110 as examples. In these claims, a composition comprising a mixture of ligands is claimed. The instant restriction requirement clearly and improperly withhold these claims from examination and consideration because there is no inclusion of this subject matter in Groups XIV to XXV as set forth.

In light of the above, Applicants respectfully, but strenuously, traverse the arbitrary restriction of the claims into Groups XIV to XXV.

Additionally, Applicant respectfully points out that the alleged basis for restriction between these Groups is misplaced. During the interview of June 8, 2006 between the undersigned and Examiners Macias and Rawling, Examiner Rawling indicated that the basis for the restriction was a need for a common structural feature as set forth in *In re Harnish* and the discussion at MPEP 803.02. But that decision and the MPEP section relate to Markush claims, and Applicants respectfully submit that no basis has been provided to support the allegation that claims 31-45, 47, 48, 50, 51, 69-82, and 90-99 are Markush claims.

Moreover, and assuming only for argument purposes that the claims are Markush claims, Applicants point out that pertinent guidance is provided in the first paragraph of MPEP 803.02 as follows:

“when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property.”

The above clearly indicates that a proper Markush grouping may be present in the absence of a common structural feature responsible for the “property in common”. . To the contrary, only presence of the “property in common” in each of the group’s members is needed. Applied to claims 31-45, 47, 48, 50, 51, 69-82, and 90-99, each of which are “combination”, or composition claims not directed to a single compound, the ligands encompassed by the claims only need have one “property in common”. In the case of at least claims 31-45, 47, 48, 50, and 51, the ligands have the binding to a pattern recognition molecule family of receptors and the ability to induce an immune response through that binding, as “properties in common”. In the case of at least claims 69-82 and 90-99, the ligands have the binding to a pattern recognition receptor molecule as a “property in common”.

Therefore, Applicant requests reconsideration and modification of the instant Restriction Requirement in favor of one group comprising all of pending claims 31-82 and 90-111.

In the event that the Restriction Requirement is maintained, Applicant elects Group XV, claims 31-82 and 90-111 where the recited ligand binds TLR-2, with traverse for the reasons provided above.

With respect to the requirement for a “Species Election” with respect to claims 31-82 and 90-111 where one of Groups XIV-XXV is elected, Applicants respectfully traverse for the same reason provided above regarding the misapprehension of the claims as Markush claims.

In the event that the requirement is for an election of species based upon the recognition of generic claims, Applicants point out that a requirement for an election of species from the genus of claimed compositions must be based upon 37 C.F.R. § 1.141(a) and 1.146, both of which expressly recognize that “a reasonable number” of species may be claimed along with an allowable generic claim within a single application. Applicant points out that there has been **no** demonstration that “more than a reasonable number of species” is encompassed by the pending claims. Therefore the requirement is deficient because no more than a reasonable number of species is presented in the pending claims.

Moreover, and as set forth at 37 C.F.R. § 1.146, election of a species is discretionary and results in a restriction *only* “if no claim to the genus is found to be allowable.” Thus Applicants respectfully submit that the requirement for an election of species is for purposes of facilitating search and examination. If no prior art is found to anticipate or render obvious the elected species, Applicants respectfully submit that the search of the claims should be extended to the next species to allow for consideration of the generic claim encompassing the species.


In light of the above, Applicant respectfully submit that the requirement for an election of species is misplaced and should be withdrawn.

Should the requirement be maintained despite the above, Applicants elect the species of "lipoprotein" as the ligand which binds a pattern recognition molecule like TLR-2 as encompassed by claims 31-59, 63-65, 69-82, 90-101, and 108-111 where at least claims 31-59, 63-65, 69-82, 90-101, and 108-111 are generic. With respect to the "antigen" in claims 69-82 and 90-111, Applicants elect the species of "virus" as encompassed by claims 69-74, 77-82, 90-101, and 108-111, where at least claims 69-74, 77-82, 90-101, and 108-111 are generic. Both of these selections are made with traverse for the reasons provided above.

Applicants reserve the right to pursue the subject matter of any non-elected claim or canceled subject matter in a subsequent divisional or other continuing application without prejudice.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,



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